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10/659,004	09/09/2003	Mei Zhong	21402-608 (Cura 908)	3491

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EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/659,004	Applicant(s) ZHONG ET AL.	
	Examiner Robert B. Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) 22,23 and 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,24 and 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*A*

## DETAILED ACTION

### *Response to restriction requirement*

Applicants' election with traverse of Invention of Group V, Claims 13-14 and 17-20 (new claims 21-38) and the further election of a nucleic acid molecule that encodes the amino acid sequence designated as SEQ ID No: 104, in amendment, filed January 28, 2005 is acknowledged. The traversal is on the ground(s) that M.P.E.P § 803.04 states " it has been determined that normally ten sequences constitute a reasonable number for examination purposes and accordingly in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction and thus, at least ten sequences should be examined in the instant application.

This is not found persuasive because the stated policy was in reference to ESTs which are much smaller molecules than the full length nucleic acid molecules that encode functional polypeptides and furthermore the M.P.E.P § 803.04 states that in most cases, **up to ten**, independent and distinct sequences and therefore, not necessarily ten nucleic acid sequences is searched for each patent application.

Also it must be noted that the data base search of full length nucleic acid molecules encoding patentable proteins does indeed impose a burden on the PTO. Financial and human resources are required to perform a thorough and accurate search of a multitude of data bases, which include international data bases and PTO's own pending data bases- this is a time consuming and resource intensive search that

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requires extremely powerful computers and expert personnel that is provided for via limited funding.

Therefore the requirement is still deemed proper and is made FINAL. **Claims 1-20** have been canceled. **Claims 21-38** are new and are pending in this application. **Claims 22-23 and 25-30** are withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. **Claims 21, 24 and 31-38** are presently under examination in accordance with the further election of a nucleic acid molecule that encodes an amino acid sequence designated as SEQ ID No: 104.

***Priority***

The current application filed on September 09, 2003 is a CIP of 10/162,335 06/03/2002 which claims benefit of 60/295,607 06/04/2001 and claims benefit of 60/295,661 06/04/2001 and claims benefit of 60/296,404 06/06/2001 and claims benefit of 60/296,418 06/06/2001 and claims benefit of 60/297,414 06/11/2001 and claims benefit of 60/297,567 06/12/2001 and claims benefit of 60/298,285 06/14/2001 and claims benefit of 60/298,556 06/15/2001 and claims benefit of 60/299,949 06/21/2001 and claims benefit of 60/300,883 06/26/2001 and claims benefit of 60/301,550 06/28/2001 and claims benefit of 60/311,972 08/13/2001 and claims benefit of 60/315,069 08/27/2001 and claims benefit of 60/315,071 08/27/2001 and claims benefit of 60/315,660 08/29/2001 and claims benefit of 60/322,293 09/14/2001 and claims benefit of 60/322,706 09/17/2001 and claims benefit of 60/341,186 12/14/2001 and claims benefit of 60/361,189 02/28/2002 and claims benefit of 60/363,673 03/12/2002 and claims benefit of 60/363,676 03/12/2002.

The current application filed on September 09, 2003 is a CIP of 10/044,564 01/11/2002 which claims benefit of 60/261,014 01/11/2001 and claims benefit of 60/261,018 01/11/2001 and claims benefit of 60/318,410 09/10/2001 and claims benefit of 60/261,013 01/11/2001 and claims benefit of 60/261,029 01/11/2001 and claims benefit of 60/261,026 01/11/2001 and claims benefit of 60/313,170 08/17/2001.

The current application filed on September 09, 2003 is a CIP of 10/094,886 03/07/2002 which claims benefit of 60/274,322 03/08/2001 and claims benefit of 60/313,182 08/17/2001 and claims benefit of 60/288,052 05/02/2001 and claims benefit of 60/318,510 09/10/2001 and claims benefit of 60/274,281 03/08/2001 and claims benefit of 60/314,018 08/21/2001 and claims benefit of 60/274,194 03/08/2001 and claims benefit of 60/274,849 03/09/2001 and claims benefit of 60/296,693 06/07/2001 and claims benefit of 60/313,626 08/20/2001 and claims benefit of 60/332,486 11/09/2001 and claims benefit of 60/275,235 03/12/2001 and claims benefit of 60/275,578 03/13/2001 and claims benefit of 60/288,228 05/02/2001 and claims benefit of 60/275,579 03/13/2001 and claims benefit of 60/312,916 08/16/2001 and claims benefit of 60/275,601 03/13/2001 and claims benefit of 60/311,978 08/13/2001 and claims benefit of 60/276,000 03/14/2001 and said 10/094,886 claims benefit of 60/276,776 03/16/2001 and claims benefit of 60/296,856 06/08/2001 and claims benefit of 60/276,994 03/19/2001 and claims benefit of 60/291,766 05/17/2001 and claims benefit of 60/277,338 03/20/2001 and claims benefit of 60/288,066 05/02/2001 and claims benefit of 60/277,239 03/20/2001 and claims benefit of 60/315,227 08/27/2001 and claims benefit of 60/318,403 09/10/2001 and claims

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benefit of 60/277,327 03/20/2001 and claims benefit of 60/277,791 03/21/2001 and claims benefit of 60/325,378 09/27/2001 and claims benefit of 60/277,833 03/22/2001 and claims benefit of 60/278,152 03/23/2001 and claims benefit of 60/310,913 08/08/2001 and claims benefit of 60/303,237 07/05/2001 and claims benefit of 60/278,894 03/26/2001 and claims benefit of 60/322,360 09/14/2001 and claims benefit of 60/279,036 03/27/2001 and claims benefit of 60/312,191 08/14/2001 and claims benefit of 60/278,999 03/27/2001 and claims benefit of 60/280,233 03/30/2001 and claims benefit of 60/303,230 07/05/2001 and claims benefit of 60/345,399 11/09/2001 and claims benefit of 60/322,296 09/14/2001 and claims benefit of 60/280,802 04/02/2001.

The current application filed on September 09, 2003 is a CIP of 10/659,004 claims benefit of 60/414,832 09/30/2002 and claims benefit of 60/409,544 09/10/2002 and claims benefit of 60/413,342 09/25/2002 and claims benefit of 60/412,767 09/23/2002 and claims benefit of 60/412,766 09/23/2002 and claims benefit of 60/411,060 09/16/2002 and claims benefit of 60/412,825 09/23/2002 and claims benefit of 60/410,320 09/12/2002 and claims benefit of 60/409,145 09/09/2002.

***Preliminary Amendment***

The preliminary amendment filed September 09, 2003 has been entered.

***Information Disclosure Statement***

The Information Disclosure Sheets (IDS)s filed August 18, 2004 has been received and is signed and considered, a copy of the Information Disclosure Sheet (IDS) is attached to the following document.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 32-33** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In **claims 32-33** the applicants cite a nucleic acid molecule that encodes an amino acid sequence, wherein the amino acid sequence differs by a single amino acid from the amino acid sequence designated as SEQ ID NO: 104 and a nucleic acid molecule that encodes an amino acid sequence that has one or more conservative substitutions to the amino acid sequence of SEQ ID NO: 104. However, the applicants have failed to provide a written description of the substitutions and deletions that would provide adequate support of the claimed invention. The applicants have not stated where (the exact position of the aa residue) in the stated amino acid sequence the

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substitution or deletion is to occur, or in the case of substitutions, the actual substituted amino acid.

Furthermore the claims are drawn to a genus of polypeptides that is defined by an unclear functional relationship to a nucleic acid molecule encoded polypeptide comprising the amino acid sequence of SEQ ID No: 104. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is that the amino acid sequences are encoded by a nucleic acid molecule, which has been subjected to undetermined substitutions and deletions. The specification does not identify any particular substitutions or deletions that must be characteristic of the claimed genus. The only adequately described species is a nucleic acid molecule encoded polypeptide comprising the amino acid sequence of SEQ ID No: 104. Accordingly, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she]



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invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a nucleic acid molecule encoded polypeptide comprising the amino acid sequence of SEQ ID No: 104, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 21, 24 and 31-38** are rejected under U.S.C 101 because the claimed invention is not supported by either specific and substantial asserted utility or well-established utility.

**Claims 21, 24 and 31-38** are directed to isolated Nov9d nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 103 that encodes the protein comprising the amino acid sequence of SEQ ID NO: 104. The instant specification discloses that the Nov9d polypeptide comprising the amino acid sequence presented in SEQ ID NO: 104 is a protein that is homologous to human LIV 1 human protein.

Pages 12-79 of the instant application describe the uses and methods of the invention, and state that the Nov9d nucleic acid molecule and protein of the invention can be used in methods such as screening, detection assays (developing products for diagnosis of diseases) predicative medicine and methods of treatment, gene therapy, tissue regeneration and that the Nov9d protein is homologous to human LIV 1 human protein. The specification also discloses that the Nov9d polypeptide can be useful for the production of antibodies used in detection assays and peptide libraries. The specification further asserts that the Nov9d peptides, Nov9d fusion proteins, Nov9d nucleotide sequences, can be used for screening of drugs effective in the treatment of the symptomatic or phenotypic manifestations of perturbing the normal function of Nov 9e polypeptide in the body and can be used directly to treat disease and disorders.

However these are not considered to be specific or substantial utilities for either the nucleic acid molecule or protein. The methods such as recombinant production of proteins, southern blotting, PCR, Elisa, polyclonal and monoclonal antibody production

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are considered to be general methods, and are not considered to be specific and substantial utilities.

It is asserted in the specification that the Nov9d polypeptide encoded by Nov9d polynucleotide is homologous to human LIV 1 human protein. The polypeptide of the invention encoded by the isolated polynucleotide sequence disclosed, has not been shown to have primary structural similarity with the polypeptide encoded by polynucleotides that encode LIV 1 human protein, or any other polypeptide that exhibits such characteristics. Also, there is no disease or disorder correlated with the Nov9d polypeptide encoded by the nucleic acid sequence of the invention. The use of unknown amino acids encoded by polynucleotides, to determine structural similarity with other amino acid sequences by itself does not constitute a specific and substantial utility. Based on, assumed yet not shown, structural similarity alone, the specification asserts that the new cDNA clone encodes a LIV 1 human protein. However function prediction from structure or structure prediction from function is not a reliable measure of utility. Nov9d human protein encoded by novel Nov9d polynucleotide has been assumed to be homologous to human LIV 1 like proteins but since the function of Nov9d polypeptide is not known it would not be conclusive to assume, solely based on structure homology, that they have the same function and would have the same utility. It is necessary to carry out further characterization of this protein to assess the patentable utility, of the polynucleotide.

The specification discloses that the Nov9e nucleic acid can be used for, production of; primers for PCR, hybridization probes for screening libraries and

expression vectors. However these are not considered to be specific and substantial utilities. The utilities described are general and would apply to any polynucleotide.

In *Brenner v. Manson*, 148 U.SP.Q 689 (Sus. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be useful because the compound produced thereby was potentially useful as anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding Nov9e human protein which have undetermined function or biological significance. Thus no actual or specific activity is attributed to the protein identified in the specification as Nov9e human protein or the polynucleotide encoding it.

In **claims 34-38** the claimed cell line comprising an expression vector comprising a promoter operably linked to the polynucleotide sequence disclosed by SEQ ID NO: 103 encoding a protein with an amino acid sequence of SEQ ID No: 104 or the complement of, is not supported by well established utility: cells may be used for expressing nucleic acid sequences but this is not a specific utility, because the use of the cell is generally applicable to any expression vector, and therefore the utility is not particular to the sequence being claimed for the cell. Moreover, the sequence itself does

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not provide for specific utility, as the function of sequence disclosed has not been determined in any art of record or shown in the application. Therefore, no specific utility is found for the claimed subject matter.

With regard to substantial utility, the claimed cell line is not supported by a substantial utility because the specification states that the cells can be used to express polypeptides of interest (pages 14-30). A starting material that can only be used to produce a final product does not have a substantial utility. In this case the DNA sequence used to produce the protein of interest does not have an asserted or identified substantial utility. The proposed research strategies to characterize potential products, specifically in regards to biological activities, do not constitute a substantial utility or a "real world use".

Because the claimed invention is not supported by a specific and substantial asserted utility for the reasons above, credibility has not been asserted. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein such that another non-asserted utility would be well established for the cell line.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 21, 24 and 31-38** are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and

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substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Even if the specification were enabling of how to use the Nov9d nucleic acid molecule and protein, enablement would not be found to be commensurate in scope with the claims. As discussed in **USC 101 and 112** rejections above, the specification has not taught the skilled artisan how to use the nucleic acid molecule and the polypeptide of SEQ ID NOs: 103 and 104 that are disclosed in the instant specification. If one skilled in the art does not know how to use the nucleic acid molecule, the skilled artisan would clearly not know how to use the nucleic acid molecule encoding a polypeptide that is homologous to human LIV 1 protein.

**Claims 21, 24 and 31-38** are rejected under 35 U.S.C 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims as presented encompass genomic DNA. The Nov9d Protein clone was obtained from a cDNA library. The structure and sequence of the chromosomal DNA is not disclosed in the sufficient detail, so that one skilled in the art can reasonably conclude that the inventors had possession of the claimed invention. The person skilled in the art would not recognize in the current disclosure a description of the invention defined by the claim as it relates to genomic DNA for several reasons. Genes are extremely complex structures made of exons (presented in cDNAs corresponding to the genomic DNA) and introns (non-coding regions between the exons). The prior art does not teach genomic DNA

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corresponding to the disclosed cDNA or a family of proteins to which the current claimed encoded protein belongs for which there is a known conservation of encoding genomic structure. There are no general rules for predicting the number of exons and introns the genomic DNA would expect to have. The prediction is even more complicated due to the possibility of splice variants, so that the disclosed cDNA may not disclose all exons within the corresponding DNA because the alternative exons are particular to individual splice variants. Even acknowledging high skill in molecular biology art, prediction of even the general structure of the claimed polynucleotide (*i.e.* number and general size of exons and introns), let alone the sequence of the polynucleotide, is not possible based on the information provided in the specification. There are no examples of genomic DNA disclosed. The coding sequences disclosed do not contain any introns sequence(s) since the sequences are cDNA, which is made of only exon sequences. It is not apparent that the claimed polynucleotide encompassing genomic DNA was obtained when the application was filed, nor was there any written description of such. For these reasons, it does not appear that applicants were in possession of the claimed invention as it pertains to genomic DNA at the time the application was filed. Because the specification merely discloses cDNA sequences, and does not describe the corresponding genomic DNAs, the written description requirement has not been met with respect to genomic DNA.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 21, 24 and 31-38** are rejected under 35 U.S.C. 102(e) as being anticipated by Mack et al. US Patent No: 6,762,020.

Mack et al. disclose nucleic acid molecules that encode an amino acid sequence that comprises the amino acid sequence of SEQ ID NO: 104 (column 51-54, SEQ ID NO: 4, nucleotides 1-357 and 1716-2265; column 47-48, SEQ ID No: 1, nucleotides 138-494 and 1853-2404).

Mack et al. teach that the nucleic acid molecules of the invention can be used to make a variety of expression vectors (column 14, lines 54-60) and that the nucleic acid molecule of the invention can include a promoter sequence optionally being an operator sequence (column 15, lines 1-15).

Mack et al. teach further that the nucleic acid molecule of the invention may be expressed in bacterial cell system (column 16, lines 46-57) or a yeast cell system (column 17, lines 11-16).



Mack et al. also teach that the nucleic acid molecule of the invention encode amino acid variants and that these variants fall within one or more of the following three classes: substitutional, insertional or deletional variants (column 18, lines 40-49).

Thus Mack et al. teach all the elements of **claims 21, 24 and 30-38** and these claims are anticipated under 35 USC 102(b).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mack et al. also teach that the nucleic acid molecule of the invention encode amino acid variants and that these variants fall within one or more of the following three classes: substitutional, insertional or deletional variants (column 18, lines 40-49).

Thus Mack et al. teach all the elements of **claims 21, 24 and 30-38** and these claims are anticipated under 35 USC 102(b).

### **Conclusion**


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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Robert B Mondesi  
Patent Examiner  
Group 1653

  
03-29-05



JON WEBER  
SUPERVISORY PATENT EXAMINER